dence. Both organizations reached the same assessment regarding clinical benefit in only 13 cases (52%). **CONCLUSIONS:** AMNOG implements a more rigorous process with respect to clinical evidence assessment compared to SMC. All AMNOG decisions are positive; however final prices may resemble generic prices for products that demonstrate low additional benefit ("Festbetragsgruppen"). In comparison, a negative decision by SMC warrants re-submission and re-assessment of the set price for successful drug reimbursement. Orphan drugs are assessed as normal products in Scotland and may be rejected on the grounds of economic evidence, while in Germany the additional benefit is presumed and price negotiation starts automatically. Furthermore, the SMC assessment process starts later than the AMNOG process.

PHP137

ACCESSING THE PHARMACEUTICAL MARKETS OF BRAZIL, RUSSIA, INDIA AND CHINA

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While pharmaceutical sales in mature economies are declining, in emerging markets they have been expanding rapidly, with growth rates in double figures. Here we focus on market access in BRIC (Brazil, Russia, India and China) which together represent just over 40% of the world population.**OBJECTIVES:** To identify the processes and key stakeholders involved in gaining market access in BRIC; to assess the importance of health technology assessment (HTA) in gaining reimbursement in these countries; to identify opportunities and challenges to market access. **METHODS:** A review was conducted to identify the current processes and key stakeholders in market access in the BRIC countries and to identify favourable and unfavourable factors to market access. **RESULTS:** The licensing and reimbursement processes vary in the BRIC countries. Brazil follows processes similar to those in Western Europe, including HTA and public consultation as part of the reimbursement application. In China, the licensing process can take 4-6 years, though fast-tracking for innovative drugs has recently been introduced. Russia, China and India do not yet rely on HTA for reimbursement decisions. In India plans to use "pharmacoeconomic principles" in setting prices of new molecules have been announced. Opportunities in all these countries result from increasing affluence and life expectancy and the diseases associated with these. Some challenges to market access are: poor IP protection; protectionist measures; compulsory licensing; drive to use generics or biosimilars, often produced locally; price controls; variable health insurance/NHS coverage; and limited budgets for prescription drugs. **CONCLUSIONS:** HTA is now common practice in Brazil, but not yet in Russia, India or China. Although demand for new drugs is increasing in these markets, protectionism measures, competition from generics and budget constraints due to the increased burden and requirement for new high priced drugs present a challenge when accessing the pharmaceutical market in BRIC countries.

PHP138

PLACEBO-CONTROLLED TRIALS: ARE THEY ACCEPTABLE TO HEALTH TECHNOLOGY ASSESSMENT BODIES?

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OBJECTIVES: The gold-standard pivotal trial design has three arms with experimental medicine, placebo and active control however, often marketing authorisation is granted on placebo controlled (PLAc) trial(s). While PLAc trials are often still acceptable to the European Clinical Trials Directive and European Medicines Agency (EMA), they are less acceptable to Health Technology Assessment (HTA) bodies. The latter request an (in)direct comparison vs. the relevant active comparator(s) (AC) to demonstrate the added value of existing standard of care. We have investigated the hurdles encountered during HTA assessments for those drugs with marketing authorization based solely on PLAc studies. **METHODS:** We identified those drugs approved since 2010 by EMA based only on PLAc trials. We then reviewed the HTA assessments for these drugs in France (HAS), Germany (G-BA) and the UK (NICE and SMC) and compared these HTA assessments to others where the trial included an AC. **RESULTS:** Applications for 41 (45 indications) of the 220 drugs approved by EMA between 2010 and end of 2012 were based exclusively on PLAc trials. The number of indications already assessed and recommended (percentage) by HTA bodies are 19 and 11 (58%) for NICE, 33 and 18 (55%) for SMC, 24 and 20 (83%) for HAS, and 18 and 12 (67%) for G-BA. When compared to all HTAs irrespective of comparator being placebo or AC assessed since 2010, lack of an AC seemed to have no impact in HAS (83% vs 75% favorable opinion among all assessments) and G-BA (67% vs 58%) assessments but had a negative impact on SMC (55% vs 85%) and NICE (58% vs 64%) recommendations. **CONCLUSIONS:** The impact of no direct comparison with an AC varies across countries. The analysis seems to indicate that in absence of head-to-head data HTA agencies will accept indirect evidence against the right AC.

PHP139

THE IMPACT OF THE ECONOMIC RECESSION AND PHARMACEUTICAL-HEALTH SERVICE AGREEMENT ON THE PROBABILITY AND TIME OF REIMBURSEMENT OF NEW MEDICINES IN IRELAND

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OBJECTIVES: To assess the impact of the Irish economic recession (September, 2008) and the Irish Pharmaceutical Healthcare Association agreement (IPHA; November, 2012) on the probability of reimbursement decided by the National Centre for Pharmacoeconomic Evaluation (NCPE). We also aim to test whether the new IPHA agreement reduced the time-to-reimbursement for new medicines in the General Medical Services (GMS) and High Tech Drug Scheme (HTDS). **METHODS:** A database of all NCPE decisions since 2006 to present was compiled from publically available NCPE decision reports and a logistic model was used to test the occurrence of the recession and the IPHA agreement on the rate of positive reimbursement made by the NCPE. We also tested whether the new agreement had an impact on the time-to-reimbursement using a linear regression model. **RESULTS:** The results of the logit model suggest that neither the economic recession nor the agreement had any statistically significant impact on the probability of reimbursement. However, there was some evidence that the time-to-reimbursement was reduced after the agreement ($p<0.10$). **CONCLUSIONS:** Although the analysis suggests that these two events had no impact on the rate of reimbursement it is possible that the reimbursement price of new drugs may have decreased over this period which could have facilitated reimbursement. Unfortunately, details of the final price of medicines are not always known in the Irish system and it is therefore not possible to test this hypothesis using currently available data. Our analysis of time-to-reimbursement suggests that the new agreement may have satisfied one of its main objectives in getting new medicines onto the market sooner.

PHP140

MODELLING THE HEALTH TECHNOLOGY ASSESSMENT (HTA) PROCESS FOR INNOVATIVE DRUG TECHNOLOGIES (IDTS) IN THE TURKISH HEALTH CARE SYSTEM

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OBJECTIVES: Offering a standardized HTA process model through economic evaluation of IDTs in the Turkish health care system. **METHODS:** Current regulations on evaluation of innovative drug technologies through the reimbursement process are defined via a process flow scheme. A stepwise model is proposed to cover a standardized HTA system within the economic evaluation through an independent HTA body (Model HTA Authority). **RESULTS:** In the current system, economic evaluation content of a reimbursement application dossier is evaluated by Social Security Institution (SSI) through Technical and Main Commissions respectively. However this evaluation process is not standardized with respect to main variables such as scientific methodologies, timelines and responsibilities. This study offers a model, which initiates a re-defined application step for economic evaluation content of a IDT reimbursement dossier; parallel application to SSI and an independent HTA body (Model HTA Authority). Therefore, the Main Commission in SSI will be able to combine a general evaluation from the Technical Commission and an HTA report of the IDT by an independent HTA body. These reports will be available to owners of reimbursement applications until announcement of a final decision of SSI, and will become publicly available afterwards. **CONCLUSIONS:** IDTs are not involved in a standardized HTA process in the current Turkish health care system. However, pharmacoeconomic analysis reports are requested by SSI for reimbursement applications of IDTs. This study offers a model, which includes a standardized HTA process for IDT in the Turkish health care system. Applicability of this model may be tested through pilot projects and further steps may be defined for further excellence.

PHP141

CANADIAN PRIVATE PAYERS' PERCEPTIONS AND EXPECTATIONS OF SUBMISSION REQUESTS FOR DRUG REIMBURSEMENT SUBMITTED BY THE PHARMACEUTICAL INDUSTRY

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OBJECTIVES: To identify, from a private payer's perspective, the required elements to include in a pharmacoeconomic model and a budget impact analysis and compare them to that of the public payers' requirements. The secondary objective was to determine the preferred components to present in a submission regarding private payers. **METHODS:** A survey was sent to 21 submission reviewers from 14 private insurance companies offering drug reimbursement, using an online survey builder, *KwikSurveys*. The survey included 15 questions divided in 5 sections: General information, Clinical information, Pharmacoeconomic evaluation, Budget impact analysis and General appreciations. **RESULTS:** Nine reviewers from eight different companies, which represent 80% of the Canadian private payer market shares, responded to the survey. Results showed that 67% of participants follow the Canadian Agency for Drugs and Technologies in Health (CADTH) guidelines for economic evaluations. 88% of participants prefer a cost-effectiveness evaluation, while 75% prefer a cost-benefit evaluation. 100% of the participants would like direct drug costs and the indirect costs related to loss of productivity due to reduced working capacity to be included in the pharmacoeconomic model. 75% would like the costs to employer to hire and train replacement worker, the costs of premiums paid to, as well as benefits received from, private insurers to also be included in the model. 63% of the participants would like to see a population data-based model for their budget impact analysis. Similarly, 63% of the participants prefer a time horizon of 3 years for the budget impact analysis. **CONCLUSIONS:** The parameters to be considered in a submission sent to private payers are different from public payers' requirements. The perspective of the pharmacoeconomic model should be that of a private payer and the budget impact analysis should only consider a population covered by private payers.

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POINT OF CARE TESTS: THE LONG AND WINDING ROAD TO REIMBURSEMENT

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OBJECTIVES: Market access for innovative new technologies can be complex and time consuming. As cost-containment pressures in the European Union (EU) intensify, evidentiary hurdles to justify new point-of-care (POC) tests continue to grow. Decentralized health care decision making can also be a significant hurdle. This study aimed to characterize the process and identify challenges for Health Technology Assessment (HTA), pricing, reimbursement, and market access for a new POC test in the EU-5 countries. **METHODS:** We conducted desktop research of